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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,449	06/28/2002	Istvan Szelenyi	033285-010	9422
21839	7590	01/24/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			KANTAMNENI, SHOBHA	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,449	SZELENYI ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's response to the Non-Final Office Action mailed on 08/08/2005.

Currently, Claims 1-4, and 7-8 are pending.

Applicant's arguments have been considered but not found persuasive, and the rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 9834595, English equivalent to US 6461591, PTO-892), the rejection of record is MAINTAINED. See under Response to Arguments.

Applicant's arguments have been considered but not found persuasive, and the rejection of Claims 7-8 under 35 U.S.C. 103(a) as being unpatentable over Keller et al. in view of Doi, Koji (WO 9831343 of record) and Bjerkec (of record) and van der Molen (of record) is MAINTAINED. See under Response to Arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (WO 9834595, English equivalent to US 6461591, PTO-892 of record).

Keller et al. discloses a inhalable medicinal aerosol composition or formulation comprising an effective amount of a beta-mimetics which is salbutamol, reproterol, salmeterol, or formoterol, and an effective amount of a corticoids which is loteprednol. See US 6461591, claims 8, 17, 3-4.

Moreover, note that it is well settled that "intended use" of a composition or product, e.g., "in the treatment of ashma brochiale", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, the disclosure of Keller et al. anticipates instant claims 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. in view of Doi, Koji (WO 9831343 of record) and Bjermer (of record) and van der Molen (of record).

The same disclosure of Keller et al. has been discussed in the 102(b) rejection set forth above.

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Keller et al. does not expressly disclose the employment of the inhalable medicinal aerosol composition comprising the combination as instantly claimed in a method for the treatment of asthma bronchiale for simultaneous, sequential or separate administration. Keller et al. does not expressly disclose a process for the preparation of the inhalable medicinal aerosol composition therein.

Doi discloses that loteprednol etabonate is known to be useful in a pharmaceutical composition and a method of treating inflammatory conditions or allergy since loteprednol etabonate has excellent anti inflammatory and antiallergic activities and its value as a drug in an ointment or a liquid form, and loteprednol etabonate is formulated into a long-term stable liquid suspension for nasal administration (see abstract page 1, 1st and 2nd paragraphs, Examples at page 7-11 claims 1-5).

Asthma bronchiale is a known inflammatory condition or allergy.

According to Bjermer, long-acting β_2 agonists, for example, salmeterol and formoterol, are bronchospasmolytics, are used as inhalations in asthma treatment. These long-acting β_2 agonists should always be given in combination with corticosteroids. Short-acting β_2 agonists, for example, salbutamol, may be given additionally (see abstract, page 587 'Introduction'; page 589, right-hand column, paragraph 4; page 590 'Conclusion'). The corticosteroids indicated include beclomethasone dipropionate, budesonide and fluticasone propionate (see page 588, left-hand column, lines 1-2; page 589, right-hand column, line 19).

The clinical study described in van der Molen shows that the symptoms of asthma patients are improved on inhalation of the long-acting β_2 agonist, formoterol in

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as addition to inhaled corticosteroids (see abstract; page 536 'Subjects'; page 538 'Discussion'). Van der Molen does not specify the corticosteroids used.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ loteprednol etabonate in combination with reproterol, salmeterol, or formoterol in a method for the treatment of allergies and/or airway disorders such as asthma bronchiale for simultaneous, sequential or separate administration.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ loteprednol etabonate in combination with reproterol, salmeterol, or formoterol in a method for the treatment of allergies and/or airway disorders such as asthma bronchiale for simultaneous, sequential or separate administration, since both loteprednol etabonate, and reproterol, salmeterol, or formoterol, are known to be useful in a pharmaceutical composition and a method for the treatment of allergies and/or airway disorders such as asthma based on the prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that combining loteprednol etabonate and reproterol, salmeterol, or formoterol both known useful for the same purpose, i.e., treating allergies and/or airway disorders such as asthma, would improve the therapeutic effects for treating the same diseases, and/or would produce additive therapeutic effects in treating the same.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third

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composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Moreover, the teachings of Bjermer and van der Molen have further clearly provided the motivation for the instant combination, because long-acting β_2 agonists, should always be given in combination with corticosteroids according to Bjermer. The clinical study described in van der Molen shows that the symptoms of asthma patients are improved on inhalation of the long-acting β_2 agonist, formoterol in addition to inhaled corticosteroids. It is noted that luteorednol etabonate is the particular corticosteroid. Further, the process for preparation of a pharmaceutical composition herein is considered well within conventional skills in pharmaceutical science.

Thus the claimed invention as a whole is seen *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

102 Rejection:

Applicant argues that "Keller discloses an inhalable medicinal aerosol formulation comprising an effective amount of a pharmaceutically active compound and a homogeneous propellant mixture, comprising carbon dioxide and hydrofluoroalkane, where the pharmaceutically active compound is either a beta-mimetic or a corticoid.... anticipation requires that every element must be disclosed or recited by the reference. Keller does not anticipate the subject matter of the present invention, as it fails to teach

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the employment of the inhalable medicinal aerosol composition, and fails to disclose a process for the preparation of the inhalable medicinal aerosol composition, as claimed in the present invention." This argument is not persuasive because Keller discloses an inhalable medicinal aerosol composition comprising an effective amount of a pharmaceutically active compound selected from the group consisting of beta-mimetics and corticoids, see claim 8, column 15, claim 3, and claim 4. It is also disclosed that the aerosol formulations can contain active compound combinations. See column 10, lines 58-61. A composition and a process for preparation of the pharmaceutical composition with a combination, comprising corticoid such as beclomethasone dipropionate, and β_2 adrenoreceptor agonist, salbutamol, in pharmaceutically acceptable excipients is disclosed. See column 14, EXAMPLE 13. Further it is respectfully pointed out that it is well settled that "intended use" of a composition or product, e.g., "in the treatment of asthma brochiale", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Thus, the disclosure of Keller et al. anticipates instant claims 1-4.

103 Rejection:

Applicant argues that "the cited references, Keller, Doi, Bjerkec and van der Molen, alone or in combination, fail to meet the requirements for a prima facie case of obviousness. The cited references fail to contain any motivation to modify said references, fail to disclose each and every one of the elements in the presently claimed

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invention, and further lack any reasonable expectation of success, should the references be so viewed" is not persuasive because Keller as discussed above discloses medicinal or pharmaceutical aerosol compositions comprising beta-mimetics and corticoids. Corticoids such as loteprednol, beclomethasone, and beta-mimetics such as salbutamol, reproterol, salmeterol, formoterol are disclosed. Bjermer, and Van der Molen teach that β_2 agonists for example salmeterol, formoterol are used as inhalations in asthma treatment, and should be given in combination with corticosteroids. Doi discloses that loteprednol etabonate is known in the method of treating inflammatory conditions or allergy (asthma bronchiale is a Respiratory disorder characterized by wheezing; usually of allergic origin). Thus from the teachings of Keller with Doi, Bjerkec, and van der Molen, one of ordinary skill in the art at the time of invention would have been motivated to combine corticosteroid loteprednol with beta-mimetics with reasonable expectation of treating asthma.

Applicant argues that "Keller fails to disclosure the certain pharmaceutical preparations for the treatment of respiratory or allergic diseases of the present invention. Thus, it would not have been obvious to combine the teachings of Keller with Doi, Bjerkec, and van der Molen" is not persuasive. It is respectfully pointed out that Keller's reference was used to show that corticoids such as loteprednol can be used in combination with the instant adrenoreceptor agonist in a pharmaceutical formulation. Thus, one of ordinary skill in the art would have been motivated to combine loteprednol with instant adrenoreceptor agonist for the treatment of asthma because Bjerkec, and van der Molen teach that adrenoreceptor agonist, for example salmeterol, formoterol

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are used as inhalations in asthma treatment, and should be given in combination with corticosteroids

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
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~~SHENGJUN WANG~~
PRIMARY EXAMINER